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Reuse of osteosynthesis plates and screws in developing countries

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Summary

When people in developing countries sustain an accident (mostly due to traffic and construction) they face a huge and difficult problem, because in general people are poor and have no insurance. They often have to refuse medical treatment, as they do not have enough money to be able to afford an operation let alone a biomaterials implant to fix their fractures. In low income countries the Gross National Income (GNI) per capita per year is US\$755 or less, while GNI in Western world is US\$23,000 and the price of a simple plate to perform an adequate osteosynthesis is in the order of US\$ 250. Therefore, people suffer from the sequelae of accidents until permanent deformities result. Some of them try to find help from a local bonesetter, but this frequently results in even more severe deformities. The devastating prospect for this patient in need of an implant while not being able to afford a new one, has lead to the extensive reuse of biomaterials as intramedullary nails or plates and screws in developing countries.

We can formulate the question whether reuse of orthopedics implants, especially plates and screws can be allowed from the standpoint of safety in bacteriological, biomechanical en metallurgical aspects. Several phenomena may prove to be inhibitory for the reuse of orthopedic implants:

1. Biological phenomena, as for instance the transmission of infective agents like fungi, bacteria, virus and virus like particles and the tissue reaction to the implant may occur which can have detrimental effects on biocompatibility after reimplantation.
2. Biomechanical phenomena like metal fatigue, loss of elasticity, breakage, scratching and cracks may seriously reduce biomechanical strength and stability.
3. Metallurgical phenomena like corrosion, release of toxic (ionic) substances into surrounding tissues and adherence of cells to the surface due to the (nano) topography.

The practice of removing an implantable product from a patient, reprocessing it, and reimplanting it into another patient, including orthopedics prostheses and dental appliances, is, surprisingly, common in several countries. In fact there are some reports which mention utilizing used biomaterials implants in their clinical research. From practical experience and from oral reports, amongst others from Surinam, Kenya, Afghanistan and Indonesia, we know that in developing countries, where reuse of plates and screws used for osteosynthesis after fractures occurs at a large scale. In many countries there seems to be a total disregard of

pertinent laws on this issue combined with a lack of institutions to enforce these laws, while there is only minimal expertise and technical support available to apply the implants.

The aim of this thesis, as outlined in **Chapter 1** on the basis of the above, is to evaluate the reusability of single use, orthopedic plates and screws used for fracture fixation.

The specific aims of the investigation are:

1. to monitor the biomechanical properties such as stiffness and metal fatigue or failure of the devices under loading conditions,
2. to compare the surface properties like roughness, wettability and element composition of new and used implants,
3. to recommend the best cleaning method based on local availability in developing countries for safe reuse of the implant.

In **Chapter 2**, a letter to the international biomaterials community is presented, asking to investigate whether there are conditions possible under which used biomaterials implants can be made suitable, with the help of the developed countries, for safe reimplantation.

Chapter 3 of this thesis aims to determine whether used plates can be safely reused in another patient from a biomechanical point of view. To this end, used osteosynthesis plates were collected from Surinam and Indonesia and subjected to different deformations in a tensile tester while registering the number of cycles until failure. Osteosynthesis plates weakened in a predictable way during use, regardless of the history of a plate, presumably because the tests were conducted under extreme conditions, in the absence of clinically applied loadsharing between bone and plate. Consequently, the data allowed a highly conservative estimate of the expected number of cycles left in a plate for a next patient of a given body weight, leaving a safety margin for the clinical situation. Although the study indicated that the history of a plate is not determinant for the number of residual cycles, multiple reuse will eventually limit the safe reuse. Therefore, it is suggested that the history of a plate is carefully registered and reuse should not be done more often than twice and never in patients with a higher body weight than the previous patients. Application of the results of this study will therewith contribute to the safe reuse of osteosynthesis plates in developing world countries.

The FDA requires that institutions or doctors who reuse single use devices (SUDs) should be able to demonstrate that physical characteristics or qualities have not been affected adversely. **Chapter 4** aims to investigate whether physico-chemical surface properties of explanted plates and screws had changed in a way impeding safe reuse in another patient. To

this end, we collected used osteosynthesis plates and screws from Indonesia and subjected them to different physico-chemical analyses. Immediately after explantation, plates and screws were mechanically cleaned and sterilized. Compared with new plates and screws, used ones were more hydrophilic as measured by water contact angles; had increased amounts of calcium-phosphates at their surfaces (X-ray photoelectron spectroscopy) including possibly pyrogenic or immunogenic material and possess a higher number of scratches (atomic force microscopy). Given that in several developing countries reuse of plates and screws is current practice, without major complications, the above alterations in surface properties may not necessarily act inhibitory toward reuse, although better cleaning methods might improve the safe use of these plates and screws.

The socio-economic conditions in many developing countries impede wide-spread general use of the assets of biomedical technology. In orthopedics this becomes evident from the large-scale, though illegal, reuse of osteosynthesis plates and screws. Although mechanical failure and infection occur more frequently than with new plates and screws, there are a sufficient number of cycles left in used plate or screw to allow one or two patients to benefit from a used plate or screw. Scientific research into the issue of the safe reuse of osteosynthesis materials from a biological point of view has never been done. Therefore the aim of **Chapter 5** is to determine whether plates and screws after simple cleaning, applying means available in developing countries, are safe from a biological point of view. Cleaning methods evaluated include a toothbrush, water, detergent and bleach. XPS analysis of cleaned surfaces and water contact angle measurements indicate that application of a toothbrush, water, and detergent yields surface characteristics similar to those of new, sterilized plates. If desired, bleach can be applied without affecting the surface properties of the materials. Subsequently, the reactivity of a mammalian monolayer in response to a used screw (ISO-10993-5) and endotoxin release (USP 27-NF 22) was evaluated, showing that all screws tested are non-cytotoxic with endotoxin release within the requirements of the FDA. Earlier we demonstrated that reuse is not necessarily impeded by mechanical weakening, provided reuse is of a plate well documented and limited. This study shows that reuse is not necessarily unsafe from a biological point of view.

In **Chapter 6** in the General Discussion the immediate cause, goal, elaboration and results of these studies are commented upon together with the formulation of the main

conclusions. Finally, in **Chapter 7**, in the Indonesian language the content of this thesis is summarized.